February 2020

Alabama State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

111 Village St • Birmingham, AL 35242 • Tel: 205/981-2280 • Fax: 205/981-2330

Technician Training Requirements for Alabama-Registered Technicians

Effective January 1, 2020, all newly registered technicians are required to complete an Alabama State Board of Pharmacy-approved training program within six months of the registration as set out in the following rule.

680-X-2-.14 The Role of Technicians in Pharmacies in Alabama

(10)(a) All technicians receiving their initial registration on or after January 1, 2020, shall complete a Board-approved training program within the first six months after their registration and submit evidence of completion to the board within 10 days of completion. The technician and the employing pharmacy shall keep documentation of this training for a period of two years from the completion of the training. The passage of a Board-recognized pharmacy technician certification examination shall be accepted as a training program. The training program shall be the responsibility of the technician and the pharmacy employing the technician. The Board of Pharmacy may issue a fine of up to one thousand ($1,000) to the pharmacy and revocation of the registration of a technician for violation of this rule

This training will ensure a **minimum** level of competency for all practicing technicians registered in the state of Alabama. It is the responsibility of the supervising pharmacist and any pharmacists supervising technicians to deliver additional training for technicians performing specialized or advanced functions as allowed by rule. **(Please refer to 680-X-2-.14 in its entirety.)**

Technicians who have completed Board-approved training, earned Pharmacy Technician Certification Board or certified pharmacy technician certifications, or registered prior to January 1, 2020, will be reflected as compliant with the training requirement on the technicians' Board of Pharmacy website profile.

To view this data:

1. Visit *www.albop.com*
2. Click "Online Services"
3. Choose "Individual Verification" from the drop-down menu
4. Input the technician license number or name of the technician and enter the verification code displayed, then click the search button
5. Identify the technician and choose the print option to view the full license details including training information for technicians

Current Board-approved training programs are listed on the Board website. Click on "Quick Links" and then choose "Board Approved Technician Training Programs." This list will be updated as more programs are approved.

Individuals or businesses wishing to receive Board approval for a program may submit a course outline, as well as course descriptions, that validates their program and educates participants on the required topics as outlined in Board Policy 19-003, listed below:

Competencies and Requirements for Pharmacy Technician Training Programs

Competencies

- Ethical, legal, and professional understanding of standards and regulations, both federal and state
- Maintaining patient privacy and confidentiality
- Role of the technician
- Terminology
- Pharmacy calculations
- Skills to read and interpret prescriptions
- Patient medication safety

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National Pharmacy Compliance News

February 2020

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.

DEA Proposes New Regulations to Address Opioid Epidemic

Drug Enforcement Administration (DEA) has announced proposed regulations to improve the agency's ability to oversee the production of opioids and other potentially dangerous drugs. The proposed regulation would further limit the quantities of medications that might be vulnerable to diversion and misuse. The proposal would also amend the manner in which DEA grants quotas to certain registered manufacturers to levels aligned with current manufacturing standards aimed at promoting quality and efficiency while also ensuring the country has sufficient quantities of Schedule II controlled substances (CS) necessary for medical, scientific, research, and industrial needs.

The proposal introduces several new types of quotas that DEA would grant to certain DEA-registered manufacturers. These use-specific quotas include quantities of CS for use in commercial sales, product development, packaging/repackaging and labeling/relabeling, or replacement for quantities destroyed. These quotas are intended to improve DEA's ability to respond quickly to drug shortages.

The proposed changes build on 2018 regulatory changes that gave a role to state attorney generals and other federal agencies in setting the aggregate production quotas for Schedule I and II CS. The proposed regulations are available in the October 23, 2019, *Federal Register* announcement at *https://www.federalregister.gov/documents/2019/10/23/2019-21989/management-of-quotas-for-controlled-substances-and-list-i-chemicals*.

FDA Issues Report on Root Causes and Solutions to Drug Shortages

Food and Drug Administration (FDA) has released a new report, *Drug Shortages: Root Causes and Potential Solutions,* which identifies root causes for drug shortages and recommends three "enduring solutions" to address the shortages. These recommendations include:

- creating a shared understanding of the impact of drug shortages on patients and the contracting practices that may contribute to shortages;
- developing a rating system to incentivize drug manufacturers to invest in quality management maturity for their facilities; and
- promoting sustainable private sector contracts (eg, with payers, purchasers, and group purchasing organizations) to make sure there is a reliable supply of medically important drugs.

In addition to these recommendations, the report outlines the agency's ongoing initiatives to mitigate drug shortages and legislative proposals in President Donald J. Trump's Fiscal Year 2020 budget. FDA also highlighted the need for international action, including global implementation of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use's (ICH's) *ICH Guideline Q12: Technical and Regulatory Consideration for Pharmaceutical Product Lifecycle Management,* which provides opportunities for regulatory flexibility in making post-approval changes to the product or its manufacturing process.

"We hope that the recommendations set forth in this report will help to set a framework that all stakeholders can assess and implement as we work together to further mitigate the public health impact that drug shortages have on American consumers," FDA stated. "In the meantime, the FDA's employees remain committed to working behind-the-scenes to anticipate and help mitigate shortages and make sure that patients have access to the drugs they need."

FDA's full statement is available at *https://www.fda.gov/news-events/press-announcements/statement-fdas-new-report-regarding-root-causes-and-potential-solutions-drug-shortages*.

HHS Announces Guide for Appropriate Tapering or Discontinuation of Long-Term Opioid Use

The United States Department of Health and Human Services (HHS) has published a new guide for clinicians intended to provide guidelines for tapering or discontinuing long-term opioid use. The guide, titled *HHS Guide for Clinicians on the Appropriate Dosage Reduction or Discontinuation of Long-Term Opioid Analgesics*, covers important issues to consider when changing a patient's chronic pain therapy. The guide also lists issues to consider prior to making a change, when initiating the change, and as a patient's dosage is being tapered, including the need to treat symptoms of opioid withdrawal and provide behavioral health support.

"Care must be a patient-centered experience. We need to treat people with compassion, and emphasize personalized care tailored to the specific circumstances and unique needs

of each patient," said ADM Brett P. Giroir, MD, assistant secretary for health in a press release. "This Guide provides more resources for clinicians to best help patients achieve the dual goals of effective pain management and reduction in the risk for addiction."

FDA Releases Draft Best Practice Document for Postmarket Drug Surveillance

As part of FDA's efforts to enhance the efficiency of its postmarket drug safety surveillance, the agency has released a new best practices document, *Best Practices in Drug and Biological Product Postmarket Safety Surveillance for FDA Staff*. The draft document outlines FDA's approach for timely postmarket analyses of drugs and biologics, and includes a high-level overview of tools, methods, and signal detection and evaluation activities, using varied data sources, for drug safety. The goal is to provide a broader context and a general overview of ongoing efforts and commitments.

"Our best practices document incorporates the guiding principle that postmarket safety surveillance is a dynamic and constantly evolving field," FDA said in a statement announcing the document's release. "By using a risk-based approach, the FDA takes into account the nature of the drug, its potential adverse events, the intended population, and the potential for serious outcomes, as well as the impact on individuals and the overall potential impact on the health of the public."

The full draft document can be accessed at *https://www.fda.gov/media/130216/download*.

FDA Issues Revised Draft Guidance on Regulation of Homeopathic Products, Withdraws 1988 Compliance Policy Guide

FDA is taking two new steps to clarifying their approach to regulating drug products labeled as homeopathic: revising draft guidance previously published in 2017, and withdrawing the Compliance Policy Guide (CPG) 400.400 issued in 1988. These moves were announced in a statement published on the FDA website. Homeopathic products are often marketed as natural alternatives to approved prescription and nonprescription products and are widely available in the marketplace. Homeopathic products, however, are marketed without FDA review and may not meet modern standards for safety, effectivity, quality, and labeling. FDA uses a risk-based approach to monitor these products and to evaluate reports of adverse events.

The revisions to the 2017 draft guidance provide further information about FDA's approach. The guidance details a risk-based enforcement policy prioritizing certain categories of homeopathic products that could pose a higher risk to public health. These include products with particular ingredients and routes of administration, products for vulnerable populations, and products with significant quality issues. FDA has invited public comment on the guidance before it is finalized. The full guidance and instructions for providing comment are available in the *Federal Register* announcement.

CPG 400.400, Conditions Under which Homeopathic Drugs May be Marketed, is being withdrawn due to inconsistency with the agency's risk-based approach to regulatory and enforcement action and is therefore being withdrawn. Specifically, FDA states that it has encountered multiple issues with homeopathic drug products posing significant risk to patients, even though the products, as labeled, appeared to meet the conditions of CPG 400.400.

DEA Warns of Increase in Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

DEA is warning health care providers and other members of the public of another increase in fraudulent phone calls attempting to extort money. Though the tactics change regularly, the callers typically claim to represent DEA and provide either fake names and badge numbers, or the names of well-known senior officials with DEA. The scammers then threaten legal action, including arrest, against the victim unless large fines are paid by wire transfer. Most recently, the scammers appear to be spoofing a DEA number based out of Salt Lake City, UT, according to a DEA press release.

The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of a legitimate investigation or legal action is always made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

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- ♦ Other site-specific competencies may be included such as processes or compounding (non-sterile and/or sterile)

Training Requirements

1. Legal and ethical questions for technicians
   a. Review federal law
      i. Learn prescription processing in compliance with federal and state regulations
      ii. Discuss controlled drugs by class, storage, ordering, record keeping, security, inventory, and punishment for violations.
   b. Review of state law as necessary for work as a pharmacy technician
      i. Activities permitted and not permitted by technician (review 680-X-2-.14)
      ii. Requirements for a legal prescription
2. Professional standards regarding the roles and responsibilities of pharmacists, pharmacy technicians, and other pharmacy employees
   a. Effective and professional verbal communication skills including conflict management
   b. [HIPAA] and confidentiality
3. Terminology
   a. Identify medical terminology specific to pharmacy including abbreviations and symbols
4. Calculations
   a. Roman and Arabic numerals
   b. Basic math skills that may include fractions, decimals, percent, ratios, proportions, calculation of quantity and days' supply, and calculation of amounts to dispense based on dosage (e.g. insulin)
5. Medication Safety
   a. Error prevention strategies for processing prescriptions
   b. Identify issues that require pharmacist intervention
   c. Look alike/sound alike medications
   d. High alert medications
   e. Leading and trailing zeros
   f. NDC or bar code safety checks

Submissions may be sent as hard copies to Donna Yeatman, Board executive secretary, at 111 Village St, Birmingham, AL 35242 or by email to dyeatman@albop.com.

Technicians who have completed training should print the "Technician Training Verification" document from the Board website (located under Applications and Forms). This document must be completed and signed by the technician and the instructor of the training or the pharmacy supervisor attesting that training was completed and the technician **is proficient in the minimum requirements** as required by the Board. Once completed, the document must be submitted to Ashley Huntley by mail at 111 Village St, Birmingham, AL 35242 or email at ahuntley@albop.com. Once all documentation is received, the technician will receive a certificate from the Board recognizing the completion of required training.

It is the responsibility of the technician, as well as the pharmacy or supervising pharmacist, to ensure that all training is completed and documented with the Board within six months of the technician's registration. It is the responsibility of the supervising pharmacist to ensure that all technicians registered with the Board for more than six months have training completed and documented by the Board prior to working in the pharmacy.

The *Alabama State Board of Pharmacy News* is published by the Alabama State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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